The Negotiated Rulemaking Committee on Special Payment Provisions for Prosthetics and Certain Custom-Fabricated Orthotics Meeting

May 19-20, 2003 – Meeting #7

Day 1 – May 19, 2003

The Negotiated Rulemaking Committee on Special Payment Provisions for Prosthetics and Certain Custom-Fabricated Orthotics convened on May 19, 2003, at the Pikesville Hilton in Pikesville, Maryland for its seventh meeting. Shortly after 9:00 a.m., Commissioners Lynn Sylvester and Ira Lobel with the Federal Mediation and Conciliation Services (FMCS) called the meeting to order and distributed the sign in sheet (Attachment 7.1) and agenda (Attachment 7.2). Mr. Lobel reviewed the minutes from the last meeting with the committee. The minutes were approved as noted (Attachment 7.3). Next, the committee heard from Ted Colaizzi, C. Peds. by The Board for Certification in Pedorthics. Mr. Colaizzi requested that certified pedorthists be considered as qualified providers for the following L-codes: L1904, L5000, L2999, and L5999. When asked why his request to include L-5000 did not fall under the shoe insert exemption clause in the statute, Mr. Colaizzi stated, "it's a prosthetic device and it's supported by the therapeutic shoe bill." In response to further inquiry regarding how the device differs from devices made by ABC/BOC certified practitioners, he stated, "L5000 is a partial shoe insert that supports the arc of the foot. The language that states 'supports the arc' is how you would distinguish the device." Various committee members expressed concern that Mr. Colaizzi's request that certified pedorthists be considered as qualified providers for specified L-codes fell outside of the committee's charge. Other members disagreed, noting that one of the codes is a prosthetic code and is therefore relevant because the law could inadvertently put C. Peds. out of business. The committee agreed it might revisit this issue at a later time.

After a short break American Occupational Therapy Association (AOTA) representative Julie Kass, referring to a letter she distributed to the committee (Attachment 7.4), expressed concern that all committee members were not negotiating in good faith. Specifically, she stated that an editorial written by member Tony Barr of the Barr Foundation (Attachment 7.5) contained inflammatory statements regarding the occupational and physical therapists' qualifications. She asked that the article be retracted. In response to her comment, Mr. Barr stated that the article was not an editorial but rather a consumer perspective. He disagreed that any of the comments were inflammatory and stated that he had an obligation to inform his constituents of the committee's proceedings. It was also noted that comments by Leslie Lloyd, AOTA, in a recent OT Weekly circulation could be seen as disparaging. In an attempt to bring this issue to closure, a suggestion was offered that the committee members refrain from putting information in print until the end of the negotiation process.

In a related discussion about "qualified providers," member Mel Stills, American Academy of Orthotists and Prosthetists, stated for the record "as a qualified ABC orthotist and by virtue of my education and training (including continuing education requirements), I'm qualified to deliver all L-codes." In response to Mr. Stills statement, Ms. Kass stated that her impression from what other members had previously stated was that many orthotists would not feel comfortable putting on a halo, for example, if they had not done it in a while or if it wasn't part of their normal practice. The real issue, some members argued, was what an individual receives at his/her basic level of education.

The committee decided to have a caucus to discuss the issue of specific L-codes that might be on its proposed list to the Centers for Medicare & Medicaid Services (CMS) and to review a proposed list of codes offered by the National Orthotic Manufacturers Association (NOMA).

Following the caucus, Dan Berish, NOMA, explained the logic behind L-codes included on NOMA's proposed list to the committee. Among his points included:

- We would not like to see anything in the law that can be made by made-to-measure types of systems.
- Anything on the list previously submitted by Terry Supan, State Boards, which uses 2-dimensional processes makes us uncomfortable but we wanted to consider other arguments in order to reach a compromise.
- We looked at diagnostic codes. For example, we looked to see where multiple joints were involved.
- Our proposal should not be viewed as a stand-alone item, but as a way to move the committee towards consensus.
- Mr. Kurlander emphasized that the various components of the negotiated rulemaking consensus agreement are not stand alone components and that any compromise suggested by NOMA on L-codes would only be made as part of a consensus agreement on all other issues. Failure to reach a consensus agreement on all issues would result in NOMA withdrawing its compromise proposal on L-codes and sticking with CMS' original 11 HCPCS codes.

Next, Mr. Supan displayed a matrix previously reviewed by the committee, which had been updated to reflect the NOMA proposal (Attachment 7.6). In response to the NOMA proposal, Kim Doolan, Barr Foundation, asked, "Why don't the multiple joints in my arm count as much as the multiple joints in my leg?" NOMA's response to her question was, "We've split the difference. It may not be entirely artful but it was the best we could do to reach a compromise." The committee agreed to review the matrix overnight.

The committee next considered the following passage:

> *In states where the provision of orthotic and prosthetic devices is regulated through state practice acts, regulations, or other statues, CMS and DMERC regulations and rules shall not supersede those state regulations. Specifically, that special payment provisions for certain custom fabricated orthotics and*

prosthetics shall be made only based on that state's practice act, regulation/administrative rules, or other statutes concerning orthoses and prostheses and who can provide them.

The review of the passage was interrupted when Dr. Hugh Hill, CMS, informed the committee that CMS could not agree to the language. He offered that CMS' advisory council draft new language for the committee to consider.

The committee next addressed the issue of "qualified supplier." Of significance were the following points:

- If you are a provider and you don't have a supplier number you cannot bill Medicare.
- The national supplier clearinghouse issues supplier numbers.
- Is the issue of qualified supplier only relevant to who can fabricate items on the L-code list?

Questions raised on the issue of qualified supplier included:
- Can a supplier bill Medicare?
- If you are a qualified provider do you have to be a qualified supplier?
- If the qualified provider doesn't fabricate an item, must a board certified facility be used in order to have Medicare pay and if so, does the supplier need a supplier number?

To consider the issue more fully, the following scenario was posed:
I'm a practitioner. I fabricate. Does my facility have to be accredited by ABC or BOC?
No- if you fabricate with your own hands.
Yes- if you are not doing the fabrication yourself (you are using others' hands).

Ms. Sylvester tried to summarize the key points by posing the following question:
Who can fabricate items on the list that Medicare will pay for?
- A qualified practitioner.
- A qualified supplier that meets national supplier clearinghouse standards.
- ABC/BOC/Third Party accreditation.
- A facility that meets such criteria as the Secretary deems appropriate. (It was asked if this was different from the third pathway?)

Ms. Sylvester asked that the group frame the questions to ensure that everyone was on the same page. Then, she explained, they could move to answering the questions. The questions are as follows:

1. If a qualified practitioner fabricates with his/her own hands,
   -Does he/she need to have a supplier number?
   -Is he/she a qualified supplier?
   -Does he/she need to work at an accredited facility (or a facility as determined by the Secretary)?

2. If a qualified practitioner uses someone else to fabricate an item (an employee who is not a qualified practitioner),
   -Do they need a supplier number?
   -Are they a qualified supplier?
   -Does the facility need to be accredited?
3. If a qualified practitioner uses central fabrication facility to fabricate an item,
   -Does the qualified practitioner have to work in an approved facility?
   -Can the central fabrication facility bill for the item?
   -Does the qualified practitioner need a supplier number?
   -Does the qualified practitioner need to qualify as a qualified supplier?
   -Is the central fabrication facility a qualified practitioner?
   -Is the central fabrication facility a qualified supplier?
4. If a qualified practitioner uses a manufacturer to fabricate an item,
   -Does the qualified practitioner have to work in an approved facility?
   -Can the manufacturer bill for the item?
   -Does the qualified practitioner need a supplier number?
   -Does the qualified practitioner need to qualify as a qualified supplier?
   -Is the manufacturer a qualified practitioner?
   -Is the manufacturer a qualified supplier?

In response to the first question, certain committee members generated the following answers:
If a qualified practitioner fabricates with his/her own hands,
-Does he/she need to have a supplier number?
Yes, either by themselves or through their employer or their business entity.
-Does he/she need to work at an accredited facility (or a facility as determined by the Secretary)?
The Secretary has deemed the current rules governing hospitals, SNF's and OT/PT practice, etc. are sufficient to meet the definition of facilities for Section 427 of BIPA.

Subcommittees were formed to address the rest of the first question and the remaining questions.

When the call for public comment was made, Mr. Jim Pior from DeRoyal addressed the committee. Mr. DeRoyal advocated for continuing education for practitioners to ensure they are familiar with new technology devices. He provided a booklet for the committee to review (Attachment 7.7)

Day 2 – May 20, 2003

The second day of the Negotiated Rulemaking Committee on Special Payment Provisions for Prosthetics and Certain Custom-Fabricated Orthotics opened with the committee convening various caucuses. The caucuses were in session for the duration of the day. Ms. Sylvester stated that the caucus groups made tremendous progress and certain

members would continue to meet after the meeting to prepare a document detailing the committee's progress. The document would form the basis of the agreement to be considered at the next meeting, scheduled for June 2-3, 2003. The document would be forwarded to committee members for review on email prior to the next meeting. At the June meeting, she explained, she expected the committee to accept or decline the agreement via an official consensus vote.

Before the meeting adjourned, Andrew Guccione, American Physical Therapy Association, distributed a handout comprising a group of letters (Attachment 7.8).

The meeting was adjourned at approximately 4:00 p.m.

List of Attachments

Attachment 7.1	Sign-In Sheet
Attachment 7.2	Agenda
Attachment 7.3	Final Minutes Meeting #6
Attachment 7.4	May 19, 2003 Letter to Committee
Attachment 7.5	Neg Reg: We Have Met the Enemy, and It Is Us! by Tony Barr
Attachment 7.6	L-Code Matrix
Attachment 7.7	DeRoyal Statement Package
Attachment 7.8	Package of Letters from Andrew Guccione
Attachment 7.9	Memo: Request from the Barr Foundation
Attachment 7.10	Public Comment Letters